WE CLAIM:
~~CLAIMS~~:

1. A recombinant or synthetic peptide or chemical equivalent thereof comprising the formula:

$$X_1X_2X_3$$

wherein:
X_1 and X_3 may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X_2 is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM).

2. A peptide molecule according to claim 1 wherein X_2 comprises from 10 to 50 amino acid residues.

3. A peptide molecule according to claim 2 wherein X_2 comprises from 10 to 30 amino acid residues.

4. A peptide molecule according to claim 3 wherein X_2 comprises from 10 to 15 amino acid residues.

5. A peptide molecule according to claim 1 or 2 or 3 or 4 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED. (SEQ ID NO:1)

6. A peptide molecule according to claim 1 or 2 or 3 or 4 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED. (SEQ ID NO:2)

7. A recombinant or synthetic peptide or chemical equivalent thereof comprising the sequence:

$$X_1X_2X_3$$

wherein:

X_1 and X_2 may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X_2 is selected from FFYTPKTRREAED (SEQ ID NO:1) and FWYIPPSLRTLED (SEQ ID NO:2), or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical IDDM.

8. A method of assaying the reactivity of a subject to IDDM autoantigen said method comprising contacting a peptide or chemical equivalent thereof comprising the formula:

$$X_1X_2X_3$$

wherein:

X_1 and X_3 may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X_2 is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM) with cells from said subject and determining reactivity by an appropriate assay.

9. A method according to claim 8 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.

10. A method according to claim 8 or 9 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

11. A method according to claim 8 wherein X_2 comprises from 10 to 50 amino acid residues.

12. A method according to claim 11 wherein X_2 comprises from 10 to 30 amino acid residues.

13. A method according to claim 12 wherein X_2 comprises from 10 to 15 amino acid residues.

14. A method according to claim 8 or 9 or 10 or 11 or 12 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED.

15. A method according to claim 8 or 9 or 10 or 11 or 12 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED.

16. A method of assaying the reactivity of a subject to IDDM autoantigen said method comprising contacting a peptide or chemical equivalent thereof comprising the formula:

$$X_1X_2X_3$$

wherein:

X_1 and X_2 may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X_2 is selected from FFYTPKTRREAED and FWYIPPSLRTLED or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with pre-clinical or clinical IDDM with cells from said subject and determining reactivity by an appropriate assay.

17. A method according to claim 16 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.

18. A method according to claim 16 or 17 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

19. Use of a peptide or chemical equivalent thereof comprising the formula:

$$X_1X_2X_3$$

wherein:

X_1 and X_3 may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X_2 is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM) to assay reactivity of a subject to IDDM autoantigen by contacting said peptide or its chemical equivalent to cells from said subject and determining reactivity by an appropriate assay.

20. Use according to claim 19 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.

21. Use according to claim 19 or 20 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

22. Use according to claim 19 wherein X_2 comprises from 10 to 50 amino acid residues.

23. Use according to claim 22 wherein X_2 comprises from 10 to 30 amino acid residues.

24. Use according to claim 23 wherein X_2 comprises from 10 to 15 amino acid residues.

25. Use according to claim 19 or 20 or 21 or 22 or 23 or 24 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED.

26. Use according to claim 19 or 20 or 21 or 22 or 23 or 24 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED.

27. Use of a peptide or chemical equivalent thereof comprising the formula:

$$X_1X_2X_3$$

wherein:

X_1 and X_2 may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X_2 is selected from FFYTPKTRREAED and FWYIPPSLRTLED or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with pre-clinical or clinical IDDM to assay reactivity of a subject to IDDM autoantigen by contacting said peptide or its chemical equivalent with cells from said subject and determining reactivity by a proliferation assay.

28. Use of a peptide or chemical equivalent according to claim 27 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.

29. Use of a peptide or chemical equivalent according to claim 27 or 28 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

9

30. A method of treatment comprising administering to a subject an effective amount of a peptide or chemical equivalent thereof for a time and under conditions sufficient to remove or substantially reduce the presence in said subject of autoreactive T-cells and/or autoantibodies to IDDM autoantigens wherein the peptide comprises the formula:

$$X_1X_2X_3$$

wherein:

X_1 and X_3 may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X_2 is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting or modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM).

31. A method according to claim 30 wherein X_2 comprises from 10 to 50 amino acid residues.

32. A method according to claim 31 wherein X_2 comprises from 10 to 30 amino acid residues.

33. A method according to claim 32 wherein X_2 comprises from 10 to 15 amino acid residues.

34. A method according to claim 30 or 31 or 32 or 33 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED. (SEQ ID NO:1)

35. A method according to claim 30 or 31 or 32 or 33 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED. (SEQ ID NO:2)

~~29~~ 31

36. A pharmaceutical composition comprising a recombinant peptide or equivalent thereof according to ~~claim 1~~ 37 or 7 and one or more pharmaceutically acceptable carriers and/or diluents.

add C1

add D1

Add I1